REMARKS

A. Status of the Claims

Currently, claims 1-20 have been cancelled and claims 21-43 are pending and presented for examination.

The Office Action of October 7, 2005 has maintained the claim rejections set forth in the Office Action of March 8, 2005. Accordingly, claims 21-25, 27-28, 31-32, and 35-43 still stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,161,095 to Brown ("Brown"), in view of U.S. Patent No. 5,642,731 to Kehr ("Kehr"). Claim 26 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown and Kehr, in view of U.S. Patent No. 5,642,731 to Cummings, Jr. ("Cummings"). Claim 29 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown and Kehr, in view of U.S. Patent No. 4,847,764 to Halvorson ("Halvorson). Claim 30 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown and Kehr, in view of Campbell (Campbell, Sandy "Accordant meets the challenges that rare chronic diseases pose for managed care", Health Care Strategic Management, August 1996). Claims 33-34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Brown and Kehr, in view of U.S. Patent No. 5,774,865 to Glynn ("Glynn").

B. Applicant's Claims Are Not Unpatentable Over The Cited References

Applicant respectfully traverses the rejections of Applicant's claims as being unpatentable over the cited references. In addition to the reasons set forth in the previous Office Action, Applicant traverse the rejections of Applicant's claims because (1) the Office Action misinterprets the Brown's use of the word "compliance" in formulating its §103 rejection; and

(2) the Office Action uses the wrong standard for establishing a prima facie case of obviousness. Accordingly, the rejections of Applicant's claims under 35 U.S.C. §103(a) should be withdrawn.

1. The Office Action's Interpretation of the Word "Compliance" Is Not Consistent with Brown's Specification

In maintaining its §103 rejection of Applicant's claims, the Office Action argues that

> Brown teaches a system that facilitates communication between patients and providers to optimize the patient's treatment and analyze patient compliance (see column 2, lines 31-37 of Brown) It appears that Applicant is suggesting that all patients using the system of Brown would never take unscheduled medications. However, if this were the case, there would be no reason to analyze compliance because all patients would only take their scheduled medication at their scheduled times. [Office Action, page 9, ¶30].

Applicant respectfully disagrees with this reasoning, for at least two reasons. First, it mischaracterizes Applicant's previous response. In that response, Applicant did not argue that "patients using the system of Brown would never take unscheduled medications", as suggested by the Office Action. Rather, Applicant argued that Brown's device is not designed for monitoring "unscheduled acts" because its only way of ensuring compliance is by providing reminders (which by definition must be pre-determined and not "unscheduled") and verifying that the patient acted in accordance with those reminders. Accordingly, Applicant argued that the Office Action's suggestion to use Brown to monitor the taking of "unscheduled medication", as suggested by Kehr, improperly violates Brown's principle of operation. See MPEP §2143.01.

Second, Applicant respectfully disagrees with the Office Action's interpretation of the text at column 2, lines 31-37 of Brown, which discusses, inter alia, "analyzing patient compliance". Based on ¶30 of the Office Action, it appears that the Office Action improperly

attributes a broader meaning to the term "compliance" than is taught by Brown. Regardless of whatever the word "compliance" may mean outside of Brown, the specification of Brown consistently uses "compliance" in the context of using reminders to prevent the patient from failing to act. Nowhere does Brown (or any other cited reference) teach that Brown's device can be used to monitor patients who are performing unscheduled acts, such as taking unscheduled medication, as suggested by the Office Action.

Brown's narrow usage of the term "compliance" (as limited to preventing a patient's failure to act) can be seen throughout Brown's specification, and is manifested in the "reminders" that Brown's device is designed to provide. The following portions of Brown's specification are illustrative:

(1) At col. 2, lines 16-21, Brown notes that "although known methods do include reminders to patients, it would be advantageous to tailor those reminders to patient's actual **compliance history** (thus providing **fewer reminders** when they are relatively less necessary and **more reminders** when they are relatively more necessary).

(2) At col. 2, lines 59-66, Brown notes that "[i]ndividuals interact with the protocol or intelligent message to provide assistance in all aspects of treatment regimen **compliance**...These aspects can include (1) **reminders regarding compliance** with a selected treatment regimen for medication, physical therapy, psychological therapy, self-improvement, or some combination thereof"

(3) At col. 5, lines 3-14, Brown notes

> Whether the portable device 112 coupled or uncoupled to the patient device 110, when the patient 111 is due to perform an act according to the

> treatment regimen, the portable device 112 uses the presentation element 117 **to provide a reminder message instructing the patient 111 to perform that act.** In a first preferred embodiment, **the act to be performed is related to compliance with a medication regimen** including, without limitation, obtaining medicine, taking medicine, taking medicine with another substance such as food or water, not taking medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill.

While Applicant has pointed to several portions of Brown's specification that show that Brown's device is designed to remind patients to act, Applicant does not see (nor has the Office Action shown) any teaching in Brown that Brown's device would be appropriate for monitoring unscheduled acts, such as taking unscheduled medication, as suggested by the Office Action. Accordingly, Applicant respectfully asserts that the Office Action interpretation of the text at column 2, lines 31-37 of Brown is incorrect, because it is inconsistent with the rest of Brown's specification.

2. The Office Action Applies the Wrong Standard In Trying to Establish a Prima Facie Case of Obviousness

In responding to Applicant's remarks in the paper submitted on July 7, 2005, the Office Action argued that "although a patient taking an unscheduled medication may violate a treatment regimen, there is absolutely nothing in the system of Brown that prevents a patient from taking unscheduled medication" [Office Action, page 9, ¶30]. The Office Action further argued that Brown's reminder messages "do not prevent a patient from taking unscheduled medication".

In making these remarks, the Office Action appears to be applying the wrong standard for establishing a prima facie case of obviousness. The mere fact that references can be combined or modified (or that nothing prevents such a combination, to use the Office Action's

own language) is not sufficient to establish a prima facie case of obviousness. For example, in In re Mills 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990), the Federal Circuit held that even if a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so" 916 F.2d at 682, 16 USPQ2d at 1432. *See* also MPEP §2143.01.

Here, however, such a suggestion or motivation is lacking, notwithstanding an assertion to the contrary by the Office Action. According to ¶32 of the Office Action,

> Kehr indicates that it would be helpful to know why a patient took a pill at an unscheduled time. When this is considered along with the fact that Brown is directed [to] both monitoring and analyzing compliance along with the ability to alter treatments based on feedback from patients (see column 2, lines 37-42 of Brown), one of ordinary skill in the art would have been motivated to combine the teachings.

The problem with this alleged motivation is that it disregards the details of operation of Brown's device. While it is true that Brown's device monitors and analyzes compliance, it always does so by first providing a reminder, and then recording the patient's response to the reminder [e.g., see Brown, col. 5, lines 24-34]. Brown does not teach that Brown's device has any capability of inputting data for compliance monitoring when the data entry is not in the context of responding to a reminder. Accordingly, Brown is not appropriate for recording unscheduled acts, and there is no teaching in any of the cited references as to how one could modify Brown's device to allow it to do so. Thus, there is no motivation to combine Brown and Kehr.

3. Applicant's Dependent Claims Are Not Unpatentable Over the Cited References

In addition to the rejections discussed in Parts B(1) and B(2) of this response, the Office Action has rejected Applicant's dependent claims 26, 29, 30, 33 and 34. In the rejection

of each of these dependent claims, the Office Action starts with the combination of Brown and Kehr, as applied to the corresponding independent claim, and adds a tertiary reference in an attempt to arrive at all of the claim elements of Applicant's dependent claims. Specifically, the Office Action relies on Cummings for a communications device coupled to a network in rejecting claim 26; on Halvorson for a database that contains a product catalog in rejecting claim 29; on Campbell for a database that is tailored to the disease hemophilia in rejecting claim 30; and on Glynn for a bar code reader and for software capable of accepting input from a patient in rejecting claims 33-34.

However, Applicant argues above that the combination of Brown and Kehr is improper for several reasons. This impropriety of the Brown/Kehr combination is not alleviated by the addition of the tertiary references, as set forth in the Office Action. Accordingly, the rejection of dependent claims 26, 29, 30, 33 and 34 under 35 U.S.C. §103(a) should be withdrawn as well.

Reconsideration and withdrawal of the rejections of these claims are respectfully requested.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

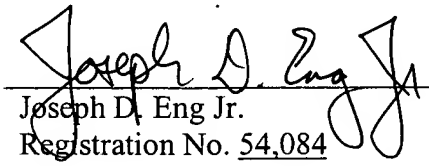
AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 4297-4017. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 4297-4017. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: January 10, 2006

By: 

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